



UNITED STATES PATENT AND TRADEMARK OFFICE

CK

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,920	07/10/2003	Chikara Uchida	PC9990B	4235
28523	7590	01/10/2006	EXAMINER	
PFIZER INC. PATENT DEPARTMENT, MS8260-1611 EASTERN POINT ROAD GROTON, CT 06340			SAEED, KAMAL A	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 01/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/617,920

Applicant(s)

UCHIDA ET AL.

Examiner

Kamal A. Saeed

Art Unit

1626

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 8-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 8-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7/10/02

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claims 1-7 and 12-13 have been cancelled. Therefore, claims 8-11 are currently pending in this application.

Information Disclosure Statement

Applicant's Information Disclosure Statements, filed on 07 October 2003 have been considered. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for treating certain diseases conditions mediated by 5-HT₄ receptor activity does not reasonably provide enablement for the prevention of all diseases mediated by this receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,

Art Unit: 1626

7. the quantity of experimentation needed, and
8. the level of the skill in the art.

The Nature of the Invention

The nature of the invention in claims 8 and 10 , is a method for the prevention of all diseases mediated by 5-HT₄ receptor. Claims 9 and 11 are directed to the prevention of diseases such as Alzheimer's disease, learning deficit, memory loss, central nervous diseases, cardiovascular disorders d etc. Even if the patient has genetic predisposition to the selected identified disease states, you are still treating the individual patient and not preventing. It has not been shown in the specification that the “**prevention**” of such diseases is accepted in the art as being predictive of the utility alleged, especially when absent of pharmacological data.

The State of the Prior Art

Alzheimer's, Huntington and Parkinson's diseases are neurodegenerative diseases. Although the clinical and neuropathological aspects of these diseases are distinct, their unifying feature is that each disease has a characteristic pattern of neuronal degeneration in anatomically or functionally related regions. Presently available pharmacological treatments for the neurodegenerative disorders are symptomatic and do not alter the course of or progression of the underlying disease (see Goodman and Gilman's, The Pharmacological Basis of Therapeutics, 10th Edition, page, 549). Therefore, the state of the art is limited to treatment of said diseases and not the prevention of said diseases.

Diseases that are affected by 5-HT₄ receptor activities are mainly gastrointestinal diseases such as Irritable bowel syndrome, constipation, impaired esophageal peristalsis etc (See British Journal of Clinical Pharmacology 2002, 54, 11-20).

The level of skill in the art

The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by *in vitro* and *in vivo* screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

The predictability or lack thereof in the art

Because of high level of unpredictability associated with “**prevention**” of certain diseases such as Alzheimer’s, a greater amount of evidentiary support is needed to fully satisfy the requirement of 35 U.S.C 112, first paragraph. It is noted that pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. In *re Fisher*, 427 F.2d 833, 166USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. The nature of pharmaceutical arts is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face.

The amount of direction or guidance present

The specification discloses methods of treating diseases such as Alzheimer’s disease, using the compounds described in the specification. The compounds which are disclosed in the

Art Unit: 1626

specification, which have data regarding treatment of diseases such as Alzheimer's (pages 9-12), have no pharmacological data regarding the prevention of said diseases. The specification is short of any data (animal models, in vitro, or in vivo testing) in regards to the prevention of said diseases. Merely stating that the instant compounds are preventable against for example Parkinson's disease does not establish usefulness of the invention absent art-recognized correlation between such tests and the ultimate use.

The presence or absence of working examples

A disclosure should contain representative examples, which provide reasonable assurance to one skilled in the art that compounds fall within the scope of a claim will possess the alleged activity. See *In re Riat et al.* (CCPA 1964) 327 F2d 685, 140USPQ 471; *In re Barr et al.* (CCPA 1971) 444 F 2d 349, 151 USPQ 724. No examples have been set forth describing the prevention of said diseases.

The breadth of the claims

As defined the claims read on treating and preventing diseases such as Alzheimer's disease, learning deficit, memory loss, attention deficit, memory loss, Parkinson's disease and Huntington's disease which is broader than the enabling disclosure.

The quantity of experimentation needed

Based on the unpredictable nature of the invention and the state of the prior art and the breadth of the claims, one of ordinary skill in the art would be burdened with undue "experimentation study" to determine whether the claimed compounds would prevent diseases such as Alzheimer's. *Genentech Inc. v. Novo Nordisk A/S* (CA FC) 42 USPQ2d 1001, states that "a patent is not a hunting license. It is not a reward for search, but compensation for its

Art Unit: 1626

successful conclusion” and “[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable”.

Therefore, in view of the Wands factors and *In re Fisher* (CCPA 1970) discussed above, to practice the claimed invention herein, a person of skill in the art would have to engage in undue experimentation to test which compounds would prevent for example Parkinson’s disease by the method encompassed in the instant claims, with no assurance of success.

It is suggested to limit the claims to the prevention of some gastrointestinal disorders that has support in the specification.

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kamal A Saeed whose telephone number is (571) 272-0705. The examiner can normally be reached on M-T 7:00 AM- 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Mr. Joseph K. McKane, can be reached at (571) 272-0699.

Communication via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by applicant and should be addressed to [joseph.mckane@uspto.gov]. All Internet e-mail communications will be made of record in the application file. PTO employees will not communicate with applicant via Internet e-mail where sensitive data will be exchanged or where there exists a possibility that sensitive data could be identified unless there is of record an express waiver of the confidentiality requirements under 35 U.S.C. 122 by the applicant. See the Interim Internet Usage Policy

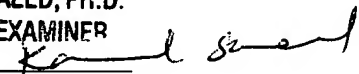
Art Unit: 1626

published by the Patent and Trademark Office Official Gazette on February 25, 1997 at 1195 OG 89.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR only. For more information about the pair system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

KAMAL A. SAEED, PH.D.

PRIMARY EXAMINER


Kamal Saeed, Ph.D.,
Patent Examiner, AU 1626